



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/279,275 | 07/22/94 | WEINER | 101016104US1 |

DARBY & DARBY
805 THIRD AVE.
NEW YORK NY 10022

HM21/0825

| EXAMINER |
|-----------------|
| ACHUTAMURTHY, P |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1648 | 56 |

DATE MAILED: 08/25/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/279,275

Applicant(s)
Weiner et al

Examiner
P. Achutamurthy

Group Art Unit
1648



☒ Responsive to communication(s) filed on Jun 11, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 9, 11-13, 15, and 20-26 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 9, 11-13, 15, and 20-26 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1648

DETAILED ACTION

This is in response to the Request for Reconsideration filed 11 June 1998. The status of the claims stand corrected as follows. Applicants are correct stating that claim 9 is still pending and that claims 16, and 17 were canceled in the amendment filed 16 September 1997. However claims 18 was also canceled in this amendment because the amendment requested cancellation claims 16-18. Accordingly claims 1, 9, 11-13, 15, and 20-26 are currently pending. It is also noted the rejection remaining is Rejection A and not Rejection B, as was inadvertently stated in the last office action.

Claim Rejections - 35 USC § 112

Rejection B

Claims 1, 9, 11-13, 15, and 20-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as stated in the previous office action (paper No. 44).

Response to Arguments

Applicant's arguments filed 11 June 1998 have been fully considered but they are not persuasive. The declaration of Dr. Weiner (third declaration) filed 11 June 1998 is acknowledged. However, the arguments and information presented to rebut the present rejection

Art Unit: 1648

is not convincing. The declaration disagrees with the Office position and opines that an immunologist in the field would have understood, based on the specification, that the method of orally administering autoantigens is not limited to treatment of EAE or multiple sclerosis, even if the etiologies of the various autoimmune diseases is different. However, to support this contention, the declaration cites examples of known treatment of T-cell mediated autoimmune diseases using agents such as cyclosporin, cyclophosphamide, methotrexate, rapamycin, FK-506, 15-deoxyspergualin. But these are therapeutically effective drugs quite different from autoantigens. While they may have immunosuppressive effects there is no reasonable basis to conclude that autoantigens would be similar to these drugs in their pharmacological actions.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1648

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P., Achutamurthy whose telephone number is (703) 308-3804. The examiner can normally be reached on Monday-Thursday from 7:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



PONNATHAPURA ACHUTAMURTHY
PRIMARY EXAMINER
GROUP 1800

pa
August 19, 1998